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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,792	01/28/2004	Daniel C. Sigg	P-11213.00	3983

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,792	SIGG ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The affidavit filed on November 17, 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Knapp et al. (U.S. 2005/0070985) (herein Knapp) reference.

2. The evidence submitted is insufficient to establish applicant's alleged actual reduction to practice of the invention in this country or a NAFTA or WTO member country after the effective date of the Knapp reference. Although Applicant does show conception of the invention prior to the effective date of Knapp, the showing of conception is not coupled with a showing or proof of due diligence from prior to the reference date to the filing date of the application (i.e. constructive reduction to practice) (see MPEP § 715.07 [R-3] and 715.07(a)).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, 16, 19, 20, 22, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp in view of Hutsell et al. (WO 95-24908) (herein Hutsell). As to Claim 1, Knapp discloses an implantable therapy delivery and/or diagnostic deice 10 comprising an elongate conductor 13 contained within a lead body 11 and a fixation element 30 adapted to secure the device to an implant site (see Knapp page 1, paragraph 10 and paragraph 13). Knapp also discloses coating 28 that covers at least a portion of the device in proximity to the implant site (see Knapp Fig. 2 and page 1, paragraph 11) and including an outer surface 40 (see Knapp

page 2, paragraph 15). Knapp further discloses that coating 28 may include a polymeric base coat that may contain a layer of a catalytic agent that is "antithrombogenic" present on the outer surface 40 of the polymeric layer 28 (see Knapp page 2, paragraph 16). Knapp discloses the claimed invention as discussed above except that the layer of a catalytic agent does not comprise nitrite reductase and/or nitrate reductase or nitrosothiol reductase activity that converts to nitric oxide when in contact with blood.

Hutsell, however, discloses the use of nitric oxide-releasing polymers to treat restenosis and other related disorders via therapeutically/prophylactically effective amount of a polymer to which is bound a nitric oxide-releasing N_2O_2 functional group or a compound comprising nitric oxide-releasing N_2O_2 functional group (see Hutsell Abstract). Hutsell also discloses that related disorders refers to conditions where the vasulature is affected by one "or more of the following": platelet aggregation, platelet adhesion, smooth muscle cell proliferation, vasoconstriction, and/or increased blood pressure whether the result of physical or chemical injury or disease (see Hutsell page 7, lines 38-39 and page 8, lines 1-5). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the antithrombogenic property of Knapp in view of Hutsell to include a catalytic agent comprising nitrite reductase and/or nitrate reductase or nitrosothiol reductase activity, that converts to nitric oxide when in contact with blood, in order to improve the inventions ability to stimulate antithrombogenic properties of endothelial cells subject to physical or chemical injury or disease.

5. As to Claim 3, see Knapp page 2, paragraphs 18-19.

6. As to Claim 16, see Knapp page 1, paragraph 3 and page 2, paragraphs 18-19.

7. As to Claim 19, Knapp further discloses that coating 28 may include a polymeric base coat that may contain a layer of a catalytic agent that is "antithrombogenic" present on the outer surface 40 of the polymeric layer 28 (see Knapp page 2, paragraph 16). The Examiner takes the position that an antithrombogenic agent is synonymous with a biocatalytic agent, which are both a biochemical catalyst.

8. As to Claim 20, Knapp further discloses that coating 28 may include a polymeric base coat that may contain a layer of a catalytic agent that is "antithrombogenic" present on the outer surface 40 of the polymeric layer 28 (see Knapp page 2, paragraph 16). The Examiner takes the position that an antithrombogenic agent is synonymous with a biomimetic catalytic agent, which are both agents that stimulate a biochemical reaction.

9. As to Claim 21, Knapp reference discloses the claimed invention except the biomimetic catalytic agent does not comprise a Cu(II) metal ion ligand complex. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the biomimetic catalytic agent from a Cu(II) metal ion ligand complex, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

10. As to Claim 25, Knapp reference discloses the claimed invention except the catalytic agent does not comprise a metal ion ligand complex. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the catalytic agent from a metal ion ligand complex, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

11. Claims 2, 23, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp in view of Hutsell and Vachon (U.S. 5,861,023). Knapp discloses that the material used to form the coating 28 may be polymers, such as silicone rubber or other insulating materials (see Knapp page 1, paragraph 10). Knapp further discloses that the material used to form the coating 28 is biocompatible and may be made from polyurethane (see Knapp page 2, paragraph 16). As to Claim 2, Knapp discloses the claimed invention as discussed above except that the material used to form the coating is not specified to be made from PTFE.

Vachon, however, discloses a thrombus and tissue ingrowth inhibiting overlay for an implatable therapy delivery and/or diagnostic device that is made from PTFE to increase conductivity of the device yet decrease tissue ingrowth (see Vachon column 1, lines 54-51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric layer of Knapp in view of Hutsell and Vachon to include a biocompatible material selected from the group consisting of silicone, polyurethane, and PTFE to increase conductivity of the device yet decrease tissue ingrowth.

As to Claims 23 and 26, Knapp discloses the claimed invention as discussed above except that the electrode does not further include a porous sidewall overlaying the layer of a catalytic agent. Vachon, however, teaches that it is well known to coat or cover an implantable device with a material such as PTFE, a porous, biocompatible insulating material that becomes conductive as body fluids penetrate the pores and inhibits tissue ingrowth. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer surface of the electrode of Knapp in view of Hutsell and Vachon to be made of porous sidewall overlaying the layer of a catalytic agent to increase conductivity of the device yet

decrease tissue ingrowth and to further comprise a polymeric plug held within the electrode sidewall to control the release of the lipophilic salts or nitrite/nitrate or nitrosothiols as they lead through the porous sidewall to the outer layer.

12. Claims 4, 5, 6, 8-10, 12, 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp in view of Hutsell and Borgersen et al. (US 2001/0018607) (herein Borgersen). As to Claims 4 and 5, Knapp discloses the claimed invention as discussed above except that the device polymeric layer 28 does not form the device body 11 and carry more than one conductor.

Borgersen, however, discloses an implantable therapy delivery and/or diagnostic device 20 comprising an elongated insulated body 40 fabricated of a plurality of co-extruded biocompatible elastomers (see Borgersen page 4, paragraph 35) such as polyurethane (see Borgersen page 6, paragraph 47) to form a multi-luminal device containing a plurality of conductors (see Borgersen page 4 paragraph 35) allowing for selective control of body stiffness for bending, torsion, axial tension or compression over the full length of the device and increased conductivity (see Borgersen page 4, paragraph 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell and Borgersen to include a polymeric layer that forms the device body as a multi-lumen tube containing one or more extending conductors to allow for selective control of body stiffness for bending, torsion, axial tension or compression over the full length of the device and to promote antithrombogenic properties over the full length of the device and increased conductivity.

13. As to Claim 6, Knapp discloses an electrode coupled an electrical conductor (see Knapp Abstract, lines 1-3) and Borgersen teaches that it is well known in the art for the body of such a device to comprise one or more insulated, conductive wires surrounded by an outer sheath (see Borgersen page 1, paragraph 3). Borgersen also teaches that electrode 42 may correspond to any conventionally available pace/sense and cardioversion/defibrillation electrodes (see Borgersen page 4, paragraph 36) and further discloses electrode 42 as a coil overlaying outer elastomer body 40 (see Borgersen Fig. 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell and Borgersen to comprise a coil electrode coupled to one of the one or more wire conductors and overlaying the outer surface of the polymeric layer forming the device body to improve the inventions conductive objectives.

14. As to Claims 8 and 9, Knapp discloses the claimed invention as discussed above except that the device does not further a polymeric layer that overlays the entire device body. Borgersen, however, discloses an implantable therapy delivery and/or diagnostic device 20 comprising an elongated insulated body 40 fabricated of a plurality of co-extruded biocompatible elastomers (see Borgersen page 4, paragraph 35) such as polyurethane (see Borgersen page 6, paragraph 47) to form a multi-luminal device containing a plurality of conductors (see Borgersen page 4 paragraph 35) allowing for selective control of body stiffness for bending, torsion, axial tension or compression over the full length of the device and increased conductivity (see Borgersen page 4, paragraph 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell and Borgersen to include a polymeric layer that overlays the device body which is a multi-lumen

tube containing one or more extending conductors, to allow for selective control of body stiffness for bending, torsion, axial tension or compression over the full length of the device and to promote antithrombogenic properties over the full length of the device and increased conductivity.

15. As to Claim 10, Knapp discloses an electrode coupled to the one of the electrical conductors (see Knapp Abstract, lines 1-3) and Borgersen teaches that it is well known in the art for the body of such a device to comprise one or more insulated, conductive wires surrounded by an outer sheath (see Borgersen page 1, paragraph 3). Borgersen also teaches that electrode 42 may correspond to any conventionally available pace/sense and cardioversion/defibrillation electrodes (see Borgersen page 4, paragraph 36) and further discloses electrode 42 as a coil overlaying outer elastomer body 40 (see Borgersen Fig. 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell and Borgersen to comprise a coil electrode coupled to one of the one or more wire conductors and overlaying the outer surface of the polymeric layer forming the device body to improve the inventions conductive objectives.

16. As to Claim 17, the previously modified Knapp reference discloses the claimed invention as discussed above except that the device does not carry more than one conductor and the conductors are not made from electrically conductive wire. Borgersen, however, discloses an implantable therapy delivery and/or diagnostic device 20 comprising an elongated insulated body 40 fabricated of a plurality of co-extruded biocompatible elastomers (see Borgersen page 4, paragraph 35) such as polyurethane (see Borgersen page 6, paragraph 47) to form a multi-luminal device containing a plurality of wire conductors (see Borgersen page 4 paragraph 35)

allowing for increased conductivity (see Borgersen page 4, paragraph 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell and Borgersen to comprise one or more wire conductors to improve the inventions conductive objectives.

17. As to Claim 18, Knapp discloses that the material used to form the coating 28 may be polymers, such as silicone rubber or other insulating materials (see Knapp page 1, paragraph 10). Knapp further discloses that the material used to form the coating 28 is biocompatible and may be made from polyurethane (see Knapp page 2, paragraph 16). The modified Knapp reference discloses the claimed invention except the polymeric plug is not formed of a material selected from the group consisting of silicone and polyurethane. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the polymeric plug from a material selected from the group consisting of silicone and polyurethane (i.e. biocompatible), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

18. Claims 7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp in view of Hutsell and Borgersen and Vachon. The modified Knapp reference differs from Claim 7 in that the coil electrode is not partially embedded in the outer surface of the polymeric layer forming the device body. Vachon, however, teaches that it is known to coat or cover a helically wound electrode with an electrically conductive polymeric material for inhibiting tissue ingrowth and for further reducing risk to the patient in the event removal of the device becomes necessary (see Vachon column 1, lines 54-61). Therefore it would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell, Borgersen, and Vachon to comprise a coil electrode coupled to one of the one or more wire conductors and partially embedded in the outer surface of the polymeric layer forming the device body to improve the inventions conductive objectives, to inhibit tissue ingrowth, and to further reduce risk to the patient in the even removal of the device becomes necessary.

19. As to Claim 11, the previously modified Knapp reference discloses the claimed invention as discussed above except that the coil electrode is not partially embedded in the outer surface of the polymeric layer forming the device body. Vachon, however, teaches that it is known to coat or cover a helically wound electrode with an electrically conductive polymeric material for inhibiting tissue ingrowth and for further reducing risk to the patient in the event removal of the device becomes necessary (see Vachon column 1, lines 54-61). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell, Borgersen, and Vachon to comprise a coil electrode coupled to one of the one or more wire conductors and partially embedded in the outer surface of the polymeric layer forming the device body to improve the inventions conductive objectives, to inhibit tissue ingrowth, and to further reduce risk to the patient in the even removal of the device becomes necessary.

20. As to Claim 12, the previously modified Knapp reference discloses the claimed invention except that the polymeric layer does not include a plurality of pores extending through it. Vachon, however, teaches that it is well known to coat or cover a helically wound implantable device with a material such as PTFE, a porous, biocompatible insulating material that becomes

conductive as body fluids penetrate the pores. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric layer of Knapp in view of Hutsell and Vachon to be made of porous PTFE to increase conductivity of the device yet decrease tissue ingrowth.

21. As to Claim 13, Knapp discloses an electrode coupled to the one of the electrical conductors (see Knapp Abstract, lines 1-3) and Borgersen teaches that it is well known in the art for the body of such a device to comprise one or more insulated, conductive wires surrounded by an outer sheath (see Borgersen page 1, paragraph 3). Borgersen also teaches that electrode 42 may correspond to any conventionally available pace/sense and cardioversion/defibrillation electrodes (see Borgersen page 4, paragraph 36) and further discloses electrode 42 as a coil overlaying outer elastomer body 40 (see Borgersen Fig. 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell and Borgersen to comprise a coil electrode coupled to one of the one or more wire conductors and overlaying the outer surface of the polymeric layer forming the device body to improve the inventions conductive objectives.

The previously modified Knapp reference discloses the claimed invention as discussed above except that the coil electrode is not partially embedded in the outer surface of the polymeric layer forming the device body and the polymeric layer does not include a plurality of pores extending through it. Vachon, however, teaches that it is known to coat or cover a helically wound electrode with an electrically conductive polymeric material for inhibiting tissue ingrowth and for further reducing risk to the patient in the event removal of the device becomes necessary (see Vachon column 1, lines 54-61). Vachon also teaches that it is well known to coat

or cover a helically wound implantable device with a material such as PTFE, a porous, biocompatible insulating material that becomes conductive as body fluids penetrate the pores. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell, Borgersen, and Vachon to comprise a coil electrode coupled to one of the one or more wire conductors and partially embedded in the outer surface of the pourous polymeric layer forming the device body to improve the inventions conductive objectives, to inhibit tissue ingrowth, and to further reduce risk to the patient in the even removal of the device becomes necessary and to improve the inventions conductive objectives.

22. Claim 15 is rejected as being unpatentable under 35 U.S.C. 103(a) over Knapp in view of Hutsell, Borgersen, and Jain et al. (U.S. 6,909,919) (herein Jain). Knapp discloses a physiological sensor 36 coupled to the one or more conductors (see Knapp Fig. 3 and page 1, paragraph 13) and coating 28 that covers at least a portion of the device in proximity to the implant site (see Knapp Fig. 2 and page 1, paragraph 11) and including an outer surface 40 (see Knapp page 2, paragraph 15). The previously modified Knapp reference discloses the claimed invention as discussed above except that the one or more conductors do not include an electrically conductive wire.

Borgersen, however, teaches that it is well known in the art for the body of such a device to comprise one or more insulated, conductive wires surrounded by an outer sheath (see Borgersen page 1, paragraph 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell and

Borgersen to comprise a physiological sensor coupled to one of the one or more wire conductors improve the inventions conductive objectives.

The modified Knapp reference also differs from Claim 15 in that the device does not include a physiological sensor capsule. Jain, however, teaches that it is well known in the art to provide a pressure sensor in the form of a non-deformable sensor capsule in order to monitor pressures in the atrial and/or ventricular chambers of the heart in assessing contractility (see Jain column 1, lines 26-29 and lines 37-39). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Knapp in view of Hutsell, Borgersen, and Jain to include a physiological sensor capsule coupled to the one or more conductors in order to improve the device's ability to monitor pressures in the atrial and/or ventricular chambers of the heart in assessing contractility.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 01/27/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766